

Exhibit E

Notice of Allowability

Application No.

09/526,193

Examiner

David J. Steadman

Applicant(s)

HAYDEN ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment H, filed 03/06/03.
2. ☒ The allowed claim(s) is/are 135,136,142-145,147-151,156-163,165,166,168,169,172-176,178-181 and 213-231.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☒ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____. | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

DETAILED ACTION

Status of the Application

- [1] Claims 135, 136, 142-145, 147-151, 156-163, 165, 166, 168, 169, 172-176, 178-181, and 213-231 are pending in the application.
- [2] Cancellation of claim 187, amendment to claims 135, 143, 161, 166, 168, 169, 172, 176, 179, 181, 184, 188, and 213, and addition of claims 226-231 in Paper No. 26, filed 03/06/03, is acknowledged.
- [3] It is noted that in a telephonic interview conducted on 02/13/03 (see attached interview summary), applicant requested a continuation of the interview due to technical difficulties with the phone line. However, a continuation of the interview of 02/13/03 has not been conducted as the outstanding issues have been resolved in the amended claims as presented in Paper No. 26 as described below.

Objection(s)/Rejection(s)

- [4] In view of applicant's amendment to claim 181, the objection is withdrawn.
- [5] In view of applicant's amendment to claims 135, 136, 142, 161-163, 165, 166, 168, 169, 172-176, and 178 the rejection under 35 U.S.C. 112, second paragraph, is withdrawn.
- [6] In view of applicant's amendment to limit the mammalian ABC1 polypeptide to a mammalian ABC1 polypeptide with at least 85% identity to SEQ ID NO:1, the rejections of claims 143-145, 148, 149, 151, 156-158, 176, 178-181, and 213-225 under 35 U.S.C. 112, first paragraph, are withdrawn.

Drawings

- [7] Receipt of corrected drawings in Paper No. 26 is acknowledged. The drawings have been objected to by the Draftsperson. See attached Form PTO-948 for details.
- [8] In a telephone conversation with Mr. Alan J. Grant on 03/27/03, it was noted by the examiner that upon entry of the latest set of corrected drawings in Paper No. 26, there are two Figure 1B's. Mr. Grant indicated that the drawing labels of Figures 1A and the first Figure 1B are in error – "Figure 1A" should be "Figure 1A-(1)" and the first "Figure 1B" should be labeled as "Figure 1A-(2)".

Art Unit: 1652

[9] It is noted that applicant should amend the Brief Description of the Drawings for Figures 1A and 1B (see page 16, line 10 of the instant specification) to reflect the corrected drawing labels as described in item 8 above.

Examiner's Amendment

[10] An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

[11] Authorization for this Examiner's amendment was given in a telephone interview with Mr. Alan J. Grant on 03/27/02.

[12] Cancel claims 184-186, 188-190, and 192-194.

[13] In claim 135, replace the first occurrence of "ABC1" in line 2 with "ATP Binding Cassette Transporter 1".

[14] In claim 161, replace "mammal" in line 3 with "human" and replace "mammalian" in line 8 with "human".

[15] In claim 166, replace "mammalian" in line 7 with "human".

[16] In claim 169, replace "ABC1 polypeptide" in line 6 with "human ABC1 protein".

[17] In claim 172, replace "ABC1 polypeptide" with "human ABC1 protein".

[18] In claim 213, insert "an" prior to "ABC1" in line 2.

Reasons for Allowance

[19] The following is an Examiner's statement of reasons for allowance. The prior art discloses mammalian ABC1 proteins, in particular a human ABC1 protein, and methods for identifying modulators thereof (see, for example, the references of Luciani et al. (*EMBO J* 15:226-235), Becq et al. (*J Biol Chem* 272:2695-2699), Hamon et al. (*Blood* 90:2911-2915), and GenBank Accession Number AJ012376 as cited in items 13-23 of Paper No. 16). However, the instant specification discloses an activity – lipid transport

Art Unit: 1652


activity - that was not previously associated with the ABC1 proteins of the prior art of record.

Furthermore, the specification discloses a previously unidentified 60 amino acids (amino acids 1-60 of SEQ ID NO:1) at the amino-terminal end of the amino acid sequence of human ABC1 (see pages 40 and 41 of the instant specification) and this additional 60 amino acids is disclosed as being involved in ABC1 lipid transport activity (see page 38 of the instant specification). While the prior art discloses mammalian ABC1 proteins, in particular a human ABC1 protein, and methods for identifying modulators thereof as stated above, the examiner can find no teaching or suggestion in the prior art of record for a human ABC1 polypeptide having amino acids 1-60 of SEQ ID NO:1, a variant of SEQ ID NO:1 with from 1-5 amino acid substitutions, or a mammalian ABC1 polypeptide having greater than 85% identity to SEQ ID NO:1 with lipid transport activity. Therefore, claims 135, 136, 142-145, 147-151, 156-163, 165, 166, 168, 169, 172-176, 178-181, and 213-231, directed to identifying modulators of ABC1 biological activity as encompassed by the claims are allowable over the prior art of record. It is noted that the intended activities encompassed by the term "ABC1 biological activity" have been clearly defined at page 15, lines 10-14 of the instant specification.

[20] Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for Group 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600
1600